DEPARTMENT OF HEALTH AND HUMAN SERVICES

920551

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

December 14, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-20

Roger D. Brock, President/Owner
Trilogy Crab Company, Inc.
P.O. Box 28486
Bellingham, Washington 98228

WARNING LETTER

Dear Mr. Brock:

On November 28, 2001, Ronald E. Gill conducted an inspection of your firm. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations [21 Code of Federal Regulations (CFR) 123]. The seafood processing regulations, which became effective on December 18, 1997, require that you have and implement written verification procedures to verify that your foreign suppliers have implemented a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP) in accordance with U.S. requirements.

The product covered during this inspection was live Dungeness Crab imported from [redacted]. At the conclusion of the inspection a list of violations (Form FDA 483) was presented to you. These HACCP violations cause your imported products to be adulterated within the meaning of 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. Specifically,

> You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health in order to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for live Dungeness Crab from Canada.

The above HACCP violation is not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the HACCP violations. Failure to promptly correct these violations may result in regulatory action without further notice such as seizure and/or injunction. Furthermore, your firm and the foreign

processor may be placed on import alert and future shipments of the product may be subject to detention without physical exam.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violation. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Althar, Compliance Officer at (425) 483-4940.

Sincerely,

Charles M. Breen
District Director

Enclosure:
Form FDA 483

cc: WSDA with disclosure statement